

APR 27 2006

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number:
		10527-637001
I hereby certify that this correspondence is being transmitted by facsimile to the United States Patent and Trademark Office on the date indicated below.  <u>04/27/2006</u> Date of Transmission  <u>Sarah E. Hoke</u> Signature  <u>SARAH E HOKE</u> Typed or Printed Name of Person Signing Certificate	Application Number  10/017,213	Filed  December 14, 2001
	First Named Inventor  Scott R. Smith	
	Art Unit  3737	Examiner  Eleni M. Mantis Mercader
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a Notice of Appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. Sec 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input type="checkbox"/> attorney or agent of record (Reg. No.)</p> <p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 Reg. No. 57,520</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.</p> <p><input type="checkbox"/> Total of no. forms are submitted.</p>		

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Attorney's Docket No.: 10527-637001 / 00-0260

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Scott R. Smith  
Serial No. : 10/017,213  
Filed : December 14, 2001  
Title : RECANALIZATION OF OCCLUDED VESSEL USING MAGNETIC  
RESONANCE GUIDANCE

Art Unit : 3737  
Examiner : Eleni M. Mantis Mercader

## MAIL STOP AF

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Pursuant to the Pre-Appeal Brief Conference Pilot Program, a request for a review of identified matters on appeal is hereby submitted with the Notice of Appeal. This pre-appeal brief is filed specifically in response to legal and factual deficiencies in the final Office Action mailed December 20, 2005. Nonetheless, all rights to address additional matters on appeal in any subsequent appeal brief are hereby reserved.

**I. The Examiner has Failed to Establish the Essential Elements for a *Prima Facie* Obviousness Rejection**

The applicant respectfully submits the Examiner has failed to show a *prima facie* case of obviousness. "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings" [MPEP, §2143]. Second, to establish a case of *prima facie* obviousness, "there must be a reasonable expectation of success". Third, "the prior art reference (or references when combined) must teach or suggest all the claim limitations" [MPEP, §2143].

## CERTIFICATE OF TRANSMISSION BY FACSIMILE

I hereby certify that this correspondence is being transmitted by facsimile to the Patent and Trademark Office on the date indicated below.

April 27, 2006  
Date of Transmission

SARAH E. HOVE  
Signature

SARAH E. HOVE  
Typed or Printed Name of Person Signing Certificate

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a. No Motivation to Combine

The Examiner is relying on a combination of five references to disclose the elements of the rejected claims. Claim 1 reads as follows:

A method of recanalizing a substantially totally occluded vessel in a subject, comprising steps of:

(a) obtaining an image from within the vessel of the substantially totally occluded vessel using magnetic resonance, including:

(i) receiving a magnetic resonance signal with an external receiver located external to the body of the subject;

(ii) generating a map image of the occluded vessel using the signal received by the external receiver;

(iii) receiving a magnetic resonance signal with a first internal antenna and a second internal antenna, the first and second internal antennae positioned within the occluded vessel and near an occlusion, where at least one of the first or the second internal antennae is an open wire length antenna; and

(iv) locally enhancing the map image of the occluded vessel using the signal received by the first and second internal antennae;

(b) guiding a recanalization device using the obtained image, the first and second internal antennae being coupled to the recanalization device; and

(c) recanalizing the occluded vessel with the recanalization device.

The Examiner relies on U.S. Patent No. 6,246,896 ("Dumoulin") to disclose a tracking coil which also delivers RF current to treat an area of interest while an MRI system acquires image data of the area of interest which depicts on the MRI image the location of the tracking coil. The Examiner concedes that Dumoulin does not teach the use of the tracking coil which provides a first image of the patient's internal area of interest used to enhance the acquired MRI image, and providing an enhanced image by combining the internal and externally derived MRI image. For this the Examiner relies on WO 98/52461 ("Minkoff"). Minkoff describes generating an MRI image of a heart using both external and internal antennas, but in a context quite different than what is claimed. In Minkoff, when imaging a patient's heart, the internal antenna can be inserted into the patient's body through the esophagus, so that the internal

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antenna can get close to the heart: the internal antenna is not within the heart (*i.e.*, the area of interest) itself. Further, Minkoff does not describe generating this image under conditions where a physician is then, in real-time, using the generated image to perform a procedure.

The Examiner relies on U.S. Patent No. 6,701,176 ("Halperin") to teach that an RF antenna can be used for internal imaging and ablation. The Examiner concedes that neither Dumoulin, Minkoff nor Halperin teach using multiple internal antennas; sub-paragraph (a)(iii) of claim 1 requires a first and a second internal antenna. The Examiner relies on U.S. Patent No. 5,964,705 ("Truwit") for incorporating multiple antennae in order to get a better image. Truwit, describes an apparatus with a pair of microcoils for MRI imaging; the preferred construction uses an opposed solenoid orientation of microcoils (Col. 4, lines 45-46). The microcoils disclosed in Truwit are not open wire length antennae. By contrast, to combine the teachings of Truwit with what is taught in Dumoulin, Minkoff and Halperin would result in an apparatus including microcoil type antennae; therefore, teaching away from what is recited in claim 1, as claim 1 requires at least one open wire length antenna. Halperin discloses a loopless type antenna, but there is no motivation to combine the teachings of Truwit with Halperin, as Truwit is directed at an improved microcoil type antenna.

With respect to the requirement of claim 1 that at least one of the internal antennae is an open wire length antenna, the Examiner relies on U.S. Patent No. 5,792,055 ("McKinnon"). The open wire length antenna of McKinnon is included on a guidewire; there is no ablation and no combining of an image obtained from the open wire length antenna with an image obtained from an external receiver.

Simply because combining five references results in a more desirable device than the devices disclosed in each reference individually is not a motivation to combine; it is an exercise in hindsight. The Examiner has pieced together discrete features from five different patents in an attempt to establish that all limitations of claim 1 are disclosed and therefore obvious (the applicant does not concede that even in combination the references disclose all the limitations of claim 1, which is discussed further below). There is no motivation provided by the references to combine all five references as suggested by the Examiner; the Examiner has impermissibly used hindsight in an attempt to reconstruct the applicant's invention. It is improper to use the applicant's disclosure as the motivation to combine the particular teachings in the cited

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references: "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure" (See, MPEP §2143, citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991)).

Further, it is respectfully submitted that merely because prior art can be modified is not sufficient to render a claim *prima facie* obvious. See MPEP §2143.01, which sets forth the applicable standard: "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination" (*In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990)).

The Examiner has similarly combined the above discussed five references to disclose the limitations of independent claims 33 and 60. Claim 33 recites a method of recanalizing a substantially totally occluded vessel in a subject. Claim 60 recites an apparatus for imaging an occluded vessel in a subject. For at least the same reasons as discussed above in reference to claim 1, the Examiner has impermissibly exercised hindsight to find a motivation to combine the five references to teach or suggest the limitations of claims 33 and 60.

The applicant respectfully submits the essential element of a *prima facie* case of obviousness of providing a motivation to combine the references has not been established by the Examiner.

b. The prior art references when combined do not teach or suggest all the claim limitations

Even in combination, the five references fail to disclose all the limitations recited in claim 1. None of the references disclose "receiving a magnetic resonance signal with a first internal antenna and a second internal antenna, the first and the second internal antennae positioned within the occluded vessel and near an occlusion ... and ... locally enhancing the map image of the occluded vessel using the signal received by the first and the second internal antennae", as required by claim 1. The reference relied on by the Examiner for disclosing enhancing an image obtained from an external receiver with an image obtained from an internal antenna is Minkoff. Minkoff does not disclose first and second internal antennae positioned with an occluded vessel and locally enhancing the map image of the occluded vessel. By contrast, Minkoff describes generating an MRI image of a heart using both external and internal antennas. In Minkoff, when imaging a patient's heart, the internal antenna can be inserted into the patient's

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body through the esophagus, so that the internal antenna can get close to the heart: the internal antenna is not within the heart (*i.e.*, the area of interest) itself.

Accordingly, at least this limitation of claim 1 is not taught or suggested by the references in combination, and again the Examiner has failed to establish all essential elements of a *prima facie* case of obviousness.

Similarly, independent claim 33 requires generating a local image of an occluded vessel using the signals received by first and second internal antennae positioned with the vessel, as well as generating a map image of the occluded vessel with an external receiver; this is not taught or suggested by Minkoff.

## II. Dependent Claims

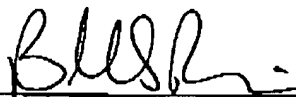
A dependent claim is neither anticipated nor rendered obvious if the independent claim upon which it depends is allowable because all the limitations of the independent claim are contained in the dependent claims (see *Hartness Int'l Inc. v. Simplimatic Eng'g Co.*, 819 F.2d at 1100, 1108 (Fed. Cir. 1987)). Accordingly, the applicant respectfully submits that claims 2-7, 9-18, 20-24, 26-32, 34-45, 47-59, 62-69 and 71-85 which depend from claims 1, 33 and 60, are allowable.

## III. Conclusion and Relief

The rejections of record are clearly improper and without basis and should be withdrawn. Moreover, it is respectfully submitted that all of the claims are in condition for allowance, and a formal notice of allowance is respectfully requested. Please apply the one month extension of time fee (\$120.00), the notice of appeal fee (\$500.00) and any other necessary charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 4-27-2006



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